Section 5 - 510(k) Summary

MAY 27 2011

Date of Summary Preparation: 11/09/2010

1. Submitter's Identifications

Submitter's Name: ZHONGSHAN TRANSTEK ELECTRONIC CO., LTD.
Address: Jinbiao Road, Minzhong, Zhongshan City, Guangdong, China
Contact Person: Guo Zhiping
Contact Email Address: gzp@transtek.cn
Telephone: 086-760-88282982 ext. 231
Fax: 086-760-85339231

2. Correspondent's Identifications

Correspondent's Name: A03 Lab of BTS
Address: No.1 Fanghua Street, Hi-tech Zone, Chengdu City, Sichuan, China
Contact Person: Leo Wang
Contact Email Address: leo.w@hibts.com
Telephone: 086-28-86083300
Fax: 086-4006070050 ext. 8

3. Name of the Device

Device Classification Name:
System, Measurement, Blood-Pressure, Non-invasive
Product Name: Blood Pressure Monitor
Trade Name: Transtek
Models: TMB-986, TMB-987, TMB-995
Classification Panel: Cardiovascular
Common/Usual Name: Automatic Blood Pressure Monitor
Product Code: DXN
Device Classification: Class II
Contraindications: None

4. The Predicate Devices

OMRON, Automatic Blood Pressure Monitor, Model HEM 780N3, K061822

5. Device Description

Transtek Blood Pressure Monitor, TMB-986, TMB-987, and TMB-995 are designed to measure the systolic and diastolic blood pressure and heartbeat rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the arm.

Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses

an electronic pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating heartbeat rate, which is a well-known technique in the market called the "Oscillometric method".

Transtek Blood Pressure Monitor is single-mounted devices of the main unit and cuff unit. ABS is used to outer housing of the main unit. The preformed cuff unit, which is applicable to arm circumference approximately between 22 and 42 cm, includes the inflatable bladder and nylon shell. All models of the arm blood pressure monitor can use the same two size of cuff (22 - 32cm, or 22 - 42cm). Product package will contains only one cuff and which size is decide by business requirement. The device consists of the microprocessor, the pressure sensor, the operation keys, the pump, the electromagnetic deflation control valve and the LCD. The subject devices are powered by four AAA or AA alkaline batteries or by a DC 6V 400mA adapter.

The device also compares the longest and the shortest time intervals of detected pulse waves to mean time interval and displays a warning signal with the reading to indicate the detection of irregular heartbeat when the difference of the time intervals is over 25%.

6. Intended Use of Device

Transtek Blood Pressure Monitor, Models TMB 986, TMB987, and TMB995 are digital monitors intended for use in measuring blood pressure and heartbeat rate in adult patient population with arm circumference ranging from 22 cm to 42 cm (about 9 - 17 inches).

These devices detect the appearance of irregular heartbeats during measurement and give a warning signal with readings.

The Blood Pressure Monitor compares average blood pressure results to pre-established AHA (American Heart Association) hypertension guideline of 135/85 mmHg.

Transtek Blood Pressure Monitor, TMB-986, TMB-987, and TMB-995 models are not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.

7. Summary of Substantial Equivalence

Table 1: The difference between Transtek Blood Pressure Monitor

<table>
<tr><td></td><td colspan="5">The Similarities and Difference among TMB-986, TMB-987 and TMB-995</td></tr>
<tr><td></td><td>Feature</td><td>TMB-986</td><td>TMB-987</td><td>TMB-995</td><td>Comparison</td></tr>
<tr><td rowspan="4">1</td><td rowspan="4">Power supply</td><td colspan="3">Battery powered mode:</td><td rowspan="2">similar</td></tr>
<tr><td>6VDC 4*AAA
alkaline batteries</td><td>6VDC 4*AAA
alkaline batteries</td><td>6VDC 4*AA
alkaline batteries</td></tr>
<tr><td colspan="3">AC adaptor powered mode:</td><td rowspan="2">similar</td></tr>
<tr><td>AC 100-240V,
50-60Hz, 400mA</td><td>AC 100-240V,
50-60Hz, 400mA</td><td>AC 100-240V,
50-60Hz, 400mA</td></tr>
</table>

3/5

	Feature	TMB-986	TMB-987	TMB-995	Comparison
2	Display mode	Digital LCD V.A.128*50mm	Digital LCD V.A.150*34mm	Digital LCD V.A.128*50mm	TMB-986, and TMB-995: 128*50mm TMB-987: 150*34mm
3	Measurement mode	Oscillographic testing mode	Oscillographic testing mode	Oscillographic testing mode	similar
4	Accuracy	Pressure: 15℃~25℃: within±0.4kpa / 3mmHg 10℃~40℃(out of 15℃~25℃): Within ±0.65kpa / 5mmHg Heartbeat: value:±5%	Pressure: 15℃~25℃: within±0.4kpa / 3mmHg 10℃~40℃(out of 15℃~25℃): Within ±0.65kpa / 5mmHg Heartbeat: value:±5%	Pressure: 15℃~25℃: within±0.4kpa / 3mmHg 10℃~40℃(out of 15℃~25℃): Within ±0.65kpa / 5mmHg Heartbeat: value:±5%	similar
5	Normal working condition	Temperature:10℃ ~40℃ Relative humidity ≤80%	Temperature:10℃ ~40℃ Relative humidity ≤80%	Temperature:10℃ ~40℃ Relative humidity ≤80%	similar
		Barometric pressure: 105~80 kPa (790~600 mmHg)			
6	Storage & transportation condition	Temperature:-20℃~60℃			similar
		Relative humidity:10~93%	Relative humidity:10~93%	Relative humidity:10~93%	
7	Measurement perimeter of upper arm	22cm~42cm	22cm~42cm	22cm~42cm	similar
8	Weight	Approx.300g (Excluding the batteries)	Approx.300g (Excluding the batteries)	Approx.300g (Excluding the batteries)	similar
9	External dimensions	Approx. 180*100*39mm	Approx. 200*60*56mm	Approx. 180*100*39mm	TMB-986, and TMB-995: Approx. 180*100*39mm TMB-987: Approx. 200*60*56mm
10	Mode of operation	Continuous operation	Continuous operation	Continuous operation	similar

Table 2: The difference between Transtek Blood Pressure Monitor and Predicate HEM 780N3

Feature	TMB-986, TMB-987, TMB-995	Predicate: HEM 780N3	Comparison
Device name	Blood Pressure Monitor	Automatic Blood Pressure Monitor	Similar
Indication for use	Measure the blood pressure and heartbeat rate. Irregular heartbeat detection.	Measure the blood pressure and heartbeat rate.	Add new features
Components	Main Unit, Cuff, Adapter, Instruction Manual, 4*AAA /4*AA batteries, Storage Case and Warranty Card	Main Unit, Cuff, Adapter, Instruction Manual, 4"AA"batteries, Storage Case and Warranty Card	Similar components and materials
Performance Tests	Biocompatibility Electromagnetic Compatibility and Electrical Safety	Biocompatibility Electromagnetic Compatibility and Electrical Safety	Similar
Labeling	Company name and address Specification Product description Indication for use Contraindications for use Precautions Warnings Safety terms and conditions Safety alert descriptions Safety and performance standards and so on	Company name and address Specification Product description Indication for use Contraindications for use Precautions Warnings Safety terms and conditions Safety alert descriptions Safety and performance standards and so on	Similar
Energy used	Battery (4*AAA/4*AA) or AC adapter (DC 6V Output)	Battery (4*AA) or AC adapter (DC 6V Output)	Similar
Display	Liquid crystal digital display	Liquid crystal digital display	Similar
Dimensions	TMB-986, TMB-995: 180(W)*100(D)*39(H)mm TMB-987: 200(W)*60(D)*56(H)mm	131(W)*155(D)*85(H)mm	Similar
Applicable cuff	Wrap around cuff	Wrap around cuff	Similar
Accuracy of pressure indicator	Within ±3mmHg(15~25℃) Within ±5mmHg (10℃~40℃(out of 15℃~25℃))	Within ±3mmHg or 2% of reading	Similar
Accuracy of heartbeat rate	Within ±5% of reading	Within ±5% of reading	Similar

Feature	TMB-986, TMB-987, TMB-995	Predicate: HEM 780N3	Comparison
Cuff inflation	Automatic inflation with air pump	Automatic inflation with air pump	Similar
Deflation of pressure	Automatic air release	Deflation rate is controlled by an active electronic control valve by 4 to 11 mmHg/s depending on pulse rate	Similar
Operating voltage	DC 6V	DC 6V	Similar
Measurement perimeter of upper arm	22cm~42cm	22cm~42cm	Similar
Operation environment	Temperature: 10℃~40℃ Relative humidity: ≤80% Barometric pressure: 105~80 kPa (790~600 mmHg)	Temperature: 10℃~40℃ Relative humidity: 30-80% Barometric pressure: 105~80 kPa (790~600 mmHg)	Similar
Transport and storage environment	Temperature: -20℃~60℃ Relative humidity:10~93%	Temperature: -20℃~60℃ Relative humidity: 10~95%	Similar

8. Conclusions

The subject devices have all features of the predicate device HEM 780N3 except the new features of irregular heartbeat detection, some specification of arm cuff and battery. These differences do not affect the safety and effectiveness of the subject devices.

Irregular heartbeat detection technology is same as what is used in Automatic Blood Pressure Monitor with Com Fit™ Cuff Model HEM-780. Thus, the subject devices are substantially equivalent to the predicate device.

--- End of this section ---

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zhongshan Transtek Electronic Co., Ltd.
c/o Mr. Leo Wang
A03 Lab of BTS
No. 1 Fanghua Street, Hi-tech District
Chengdu City, Sichuan
CHINA

MAY 27 2011

Re: K101681
Trade/Device Name: Transtek Blood Pressure Monitor Models TMB-986, TMB-987 and TMB-995
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Monitoring System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: Undated
Received: May 13, 2011

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use

510(k) Number (if known): K101681

Device Name: Blood Pressure Monitor
Models: TMB-986, TMB-987, TMB-995

Indications for Use:

This series of devices are digital monitors intended for use in measuring blood pressure and heartbeat rate in adult patient population with arm circumference ranging from 22 cm to 42 cm (about 9 - 17 inches).

These devices detect the appearance of irregular heartbeats during measurement and give a warning signal with readings.

The Blood Pressure Monitor compares average blood pressure results to pre-established AHA (American Heart Association) hypertension guideline of 135/85 mmHg.

Transtek Blood Pressure Monitor, TMB-986, TMB-987, and TMB-995 models are not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101681